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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,857	12/12/2001	Antonio Bosetto	02508.0090	5464
22852	7590	06/16/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/913,857	BOSETTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia M. Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> .                  |

## DETAILED ACTION

### *Response to Amendment*

In the amendment filed 10/01/04, claims 1-12 were cancelled and new claims 13-43 were added. A new abstract was submitted and portions of the specification were amended.

### *Specification*

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542. The following means-plus-function claim recitations do not comply with 35 U.S.C. 112, sixth paragraph:

- i) means for inducing &/or inducing means
- ii) means for determining &/or determining means

- iii) means for calculating
- iv) means for acquiring &/or acquiring means
- v) means for controlling
- vi) means for causing a succession of changes

Appropriate correction is required.

### ***Claim Objections***

Claims 28-43 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

The following means-plus-function claim recitations do not comply with 35 U.S.C. 112, sixth paragraph:

- i) means for inducing &/or inducing means
- ii) means for determining &/or determining means
- iii) means for calculating
- iv) means for acquiring &/or acquiring means
- v) means for controlling
- vi) means for causing a succession of changes

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 40, 42, & 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims recite that the blood parameter is hemoglobin concentration. This limitation is not supported in the disclosure of the originally filed specification.

Claims 19, 24, 25, 34, 35, 38, 39, & 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims recite means for acquiring or acquiring means. This limitation is not supported in the originally filed specification.

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Claims 14 & 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims recite that measurements are made in first and second cycles. This limitation is not supported in the originally filed specification.

Claims 13-15, 19-24, & 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims recite that first and second values of the blood parameter are measured. This limitation is not supported in the originally filed specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 recites the limitation "the hemoglobin concentration" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation "the blood temperature" in line 2 of the claim.

There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "the hemoglobin concentration" in lines 2 & 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 5-6 of claim 27, the recitation of "an ultrafiltration flow ultrafiltered in a blood treatment device arranged between the withdrawal line and the return line" is unclear. Is this an ultrafiltration filter between the lines? Or an ultrafiltered fluid administered between the lines? Clarification is required.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Krämer (5,866,015). Krämer discloses a method for determining hemodynamic parameters during extracorporeal hemotherapy. Blood is circulated through a circuit at a desired blood flow rate, said circuit including an arterial line, a venous line, a blood treatment unit (such as dialyzer) having multiple compartments, and a fistula connecting a patient to undergo treatment to the circuit. A blood parameter, such as a concentration of a blood constituent, flow or hematocrit, is measured using well-known measuring sensors. Multiple values are measured and the exact value is determined by a linear equation or extrapolation. A control unit alters the delivery rate of the blood pump, which inherently varies the ultrafiltration rate through the dialysis membrane. Thus, when the blood flow rate is varied by the system the ultrafiltration rate is also varied. The control system has a memory unit for storing the measured values and a processor unit to determine the measured value of the desired parameter. The processor arithmetically determines the actual value for the parameter by using the different or varied blood flow rates and the measured values. Krämer also discloses that there is no need to add an indicator solution for the measurements to be made. Krämer substantially discloses the invention as claimed except for distinctly indicating that there are disturbance induced causes a variation of, or a succession of changes, in the concentration of hemoglobin in the blood. It is the position of the examiner that Krämer inherently teaches taking multiple



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measurements of a blood parameter, which inherently includes at least one or a succession of variations of hemoglobin concentration as said parameter. It is also inherent that the measured parameter can be of hemoglobin since the disclosure sets forth measuring a concentration of a blood component. If applicant disagrees that the above measurements of hemoglobin concentration are not inherently taught by Krämer, then it would have been obvious to one having ordinary skill in the art to choose to make measurements of hemoglobin concentration variation to be used in the calculation as the desired parameter based on the design of a patient's treatment.

### ***Response to Arguments***

Applicant's arguments filed 10/01/04 have been fully considered but they are not persuasive. Applicant argues that Krämer does not teach of a device and method for generating a succession of increases and decreases of a value of a blood parameter around an average value or a predetermined profile, wherein each variation has an increase and decrease of the blood parameter value. The examiner respectfully disagrees. Since Krämer inherently teaches taking multiple measurements of a blood parameter, which inherently includes at least one or a succession of variations of hemoglobin concentration as said parameter, the claim limitations are met. Further, since Krämer teaches of changing the ultrafiltration flow rate and a curve is generated, it is inherent that multiple variations are carried out.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 10<sup>th</sup>, 2005

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**

Patricia M Bianco  
Primary Examiner  
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